JS 44 (Rev. 04/21)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS
Westfield Foot & Ankle Specialists, LLC

(b) County of Residence of First Listed Plaintiff Union
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Dominic A. DeLaurentis, Jr., Esq.
Stahl & DeLaurentis, PC 856) 380-9200
500 Grove Street, Suite 400
Haddon Heights, NJ 08035

DEFENDANTS Centers for Medicare and Medicaid Services
Dr. Mehmet Oz, Administrator;
US Department of Health & Human Services
Robert F. Kennedy, Jr. Secretary

County of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☒ 2 U.S. Government Defendant
- ☐ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*
Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☒ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

INTELLECTUAL PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent - Abbreviated New Drug Application
- ☐ 840 Trademark
- ☐ 880 Defend Trade Secrets Act of 2016

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit (15 USC 1681 or 1692)
- ☐ 485 Telephone Consumer Protection Act
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS
Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*: 28 USC Section 1331 (Federal question) and 28 USC Section 1361 (Mandamus Act) and 28USC Section 2201-02

Brief description of cause: Seeking Mandamus to enforce the 8/16/24 Decision of the Hon. Ell Bruch, ALJ

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.

DEMAND $ $239,477.74

CHECK YES only if demanded in complaint:
JURY DEMAND: ☐ Yes ☐ No

VIII. RELATED CASE(S) IF ANY *(See instructions):*

JUDGE _____ DOCKET NUMBER _____

DATE SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

#18725

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

Plaintiff WESTFIELD FOOT & ANKLE SPECIALISTS, LLC 592 B. Springfield Avenue, Suite A Westfield, NJ 07090 c/o MARSHALL COOPER, DPM 4467 East Road Shaftsbury, VT 05262 vs. *Defendants* DR. MEHMET OZ, Administrator Centers for Medicare and Medicaid Services (CMS) 7500 Security Blvd. Baltimore, MD 21244-1850 Robert Kennedy, Jr., Secretary US Department of Health and Human Services (HHS) 200 Independence Ave SW Washington, DC 20201	CIVIL ACTION NO.: **COMPLAINT FOR MANDAMUS AND DECLARATORY RELIEF**

I. PRELIMINARY STATEMENT

1. This case involves 4 New Jersey patients treated by plaintiff in Westfield, New Jersey and 35 claims for that treatment dating from September 2, 2020 to September 8, 2021. Medicare initially paid the claims then later denied the claims in their entirety.

2. The amount of claimed overpayment to plaintiff according to CMS was $345,533.46. This amount was repaid by plaintiff to Medicare, prior to the appeal process, to avoid the assessment of interest.

3. Ultimately the matter was heard by way of an Administrative Law Judge Hearing on June 12, 2024 before the Hon. Eli Bruch, ALJ. Plaintiff was provided with Judge Bruch's 35 page written opinion on August 16, 2024.

4. No appeal was taken from Judge Bruch's decision. Calculations from Judge Bruch's decision reflect that Westfield Foot & Ankle Specialists, LLC should be refunded $239,477.74. Neither HHS nor CMS have complied with Judge Bruch's decision, despite written request that they do so.

5. Accordingly, this is an action for declaratory and mandamus relief against the Secretary of Health and Human Services and the administrator of CMS as the officials responsible for implementing and enforcing the Medicare program, including following the decision duly issued by ALJ Bruch.

II. JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction under 28 USC §1331 (federal question) and 28 USC §1361 (Mandamus Act). This Court has additional remedial authority under 28 USC §2201-02 (Declaratory Judgment Act).

7. Venue is proper in the District of New Jersey under 28 USC§1391(e)(1) because a substantial part of the events or omissions giving rise to the claim occurred in New Jersey, namely the treatment at issue was in New Jersey to New Jersey patients. Each defendant is an officer of the United States sued in their official capacity.

III. FACTUAL BACKGROUND

8. This case involves podiatric services rendered by plaintiff to four medicare beneficiaries (EA, JD, AL, HO) dating from September 2, 2020 to September 8, 2021 encompassing 35 claims.

9. Initially, the Medicare Administrative Contractor allowed payment for the services at issue. However, on November 23, 2021, Safe Guard Services, LLC, the CMS Unified Program Integrity Contractor (UPIC) reopened the claims ultimately denying them in their entirety.

10. The original claimed amount of overpayment according to CMS was $345,533.46. This amount was repaid by plaintiff to medicare prior to the appeals process. (Exhibit "A"). This repayment was to avoid possible interest.

11. The Medicare programs system of administrative review has 5 levels of appeal. The third level of appeal is review by an Administrative Law Judge which is the decision involved in this case. (Exhibit "B", ALJ Eli Bruch's Decision served on plaintiffs on 8/16/24).

12. The time limit for filing a request for review by the fourth level of appeal, Departmental Appeals Board (DAB) Review/Appeals Council is 60 days from the August 16, 2024 date of receipt of the ALJ decision. That time period has expired with no party having filed a fourth level appeal. Thus, Judge Bruch's decision is binding on CMS and plaintiff.

13. Of the 35 claims at issue, Judge Bruch found 23 of 35 claims favorable to plaintiff (Exhibit "B").

14. Calculations from Judge Bruch's August 16, 2024 decision denote that plaintiff should be refunded $239,477.74 of the $345,533.46 that plaintiff had previously repaid to defendant by check of June 15, 2022 to Novitas.

15. Subsequent to the expiration of the 60 day time period to appeal Judge Bruch's decision, plaintiff contacted medicare on 8 occasions to determine when plaintiff would receive its refund. (Exhibit "C" to attached letter of 1/1/25).

16. It was not until December 26, 2024 that plaintiff was provided with a spreadsheet by medicare's agent, Novitas, where they in error, contrary to Judge Bruch's decision, found that no refund was due to plaintiff (Exhibit "C").

17. The erroneous deductions CMS made were as follows: (Exhibit "C").

Deduction for 2 patients (LB and LC) who were not part of the audit nor a prior claim made by CMS against plaintiff for these patients-dates of service.	$154,301.16
Deduction for patient EA for 7/22/21 that was not a date of service questioned or audited by CMS and thus was not part of Judge Bruch's decision	$12,072.64
Deduction for patient EA for dates of service 8/20/21, 8/13/21 and 8/27/21 where Judge Bruch had ruled in favor of plaintiff	$15,798.53
CMS improper refusal to reimburse plaintiff for all services provided to HO which were all deemed favorable by Judge Bruch (See Exhibit "B", pg. 23)	$57,305.61
TOTAL DUE TO PLAINTIFF	$239,477.74

IV. FIRST CAUSE OF ACTION-MANDAMUS

18. The foregoing allegations are repeated and incorporated as though fully set forth herein.

19. Defendants owe plaintiff a non-discretionary duty to comply with Judge Bruch's August 16, 2024 decision (Exhibit "B") and make payment to plaintiff for services found favorable in the amount of $239,477.74.

20. Plaintiff is thus entitled to a writ of mandamus under 28 USC §1361 and 1651. Plaintiff has no adequate remedy at law. Only declaratory and mandamus relief that this Court can provide will fully redress the wrong done to plaintiff. Plaintiff has no other means to

compel defendants to perform the nondiscretionary duty they, as Administrator of CMS and Secretary to HHS, owe to plaintiff.

V. PRAYER OF RELIEF

WHEREFORE, plaintiff respectfully requests that this Court:

1. Issue a writ of mandamus pursuant to 28 USC §1361 and 1651, directing defendants to comply with Judge Bruch's August 16, 2024 decision and to make payment to plaintiff in the amount of $239,477.74 per Judge Bruch's decision;

2. Retain jurisdiction over this action and any attendant proceedings until defendants have fully complied with Judge Bruch's August 16, 2024 decision;

3. Award plaintiff attorney's fees and costs pursuant to 28 USC§2412; and

4. Award such other and further relief that the Court may deem just and proper.

STAHL & DELAURENTIS, P.C.

Date: 5/5/25

Dominic A. DeLaurentis, Jr.

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EXHIBIT "A"

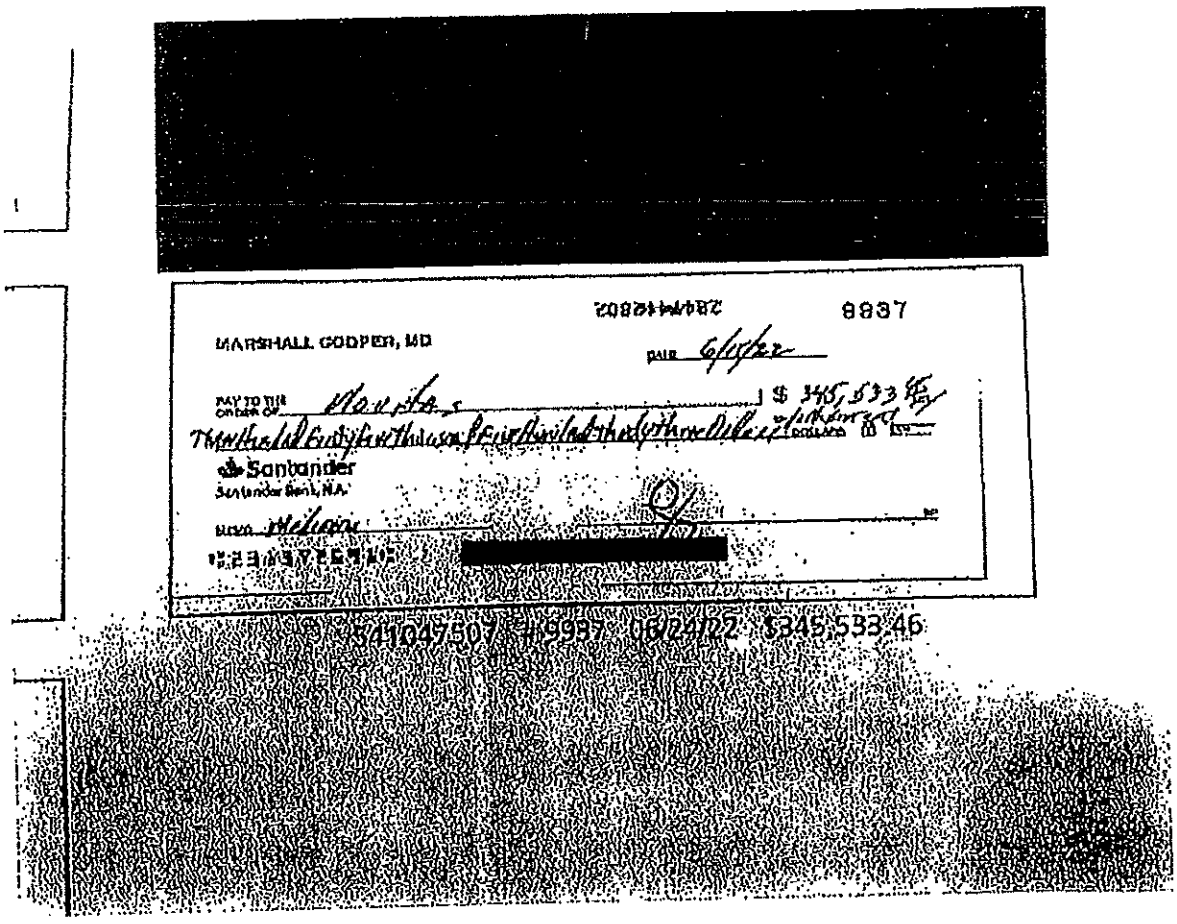
MARSHALL COOPER, MD
9937
Santander
Santander Bank, N.A.
541047507 9937 06/24/22 $345,533.46

EXHIBIT "B"

Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Phoenix, AZ

Appeal of:	WESTFIELD FOOT & ANKLE SPECIALISTS, LLC	OMHA Appeal No.:	3-12502456807
Beneficiary:	Multiple (See Attachment A)	Medicare Part:	B
Medicare No.:	Multiple (See Attachment A)	Before:	ELI BRUCH Administrative Law Judge

DECISION

After careful consideration of the applicable law, regulations, written guidelines, documentary evidence, and argument in the record, a **PARTIALLY FAVORABLE** decision is entered for **Westfield Foot & Ankle Specialists, LLC** ("Appellant"). However, liability is limited with respect to the beneficiaries, and the Appellant remains financially responsible for the non-covered charges under Section 1879 of the Social Security Act ("Act"). The Appellant is also not without fault in causing the overpayment under Section 1870 of the Act.

No.	Initials	Dates of Service	HCPCS/CPT Codes	Claims	ALJ Disposition
1	E.A.	07/09/21 – 08/27/21	15275, Q4197	6	Partially Favorable
2	J.D.	09/02/20 – 03/17/21	15275, Q4159, Q4197	9	Favorable
3	A.L.	03/10/21 – 09/08/21	15275, Q4159, Q4197	16	Unfavorable
4	H.O.	01/21/21 – 03/19/21[1]	15277, Q4159	4	Favorable

PROCEDURAL HISTORY

This is an appeal before the Office of Medicare Hearings and Appeals (OMHA) on a timely request for hearing filed by the Appellant regarding Medicare coverage of skin substitute graft applications (15275, 15277), Affinity amniotic membrane allograft (Q4159), and PuraPly XT antimicrobial wound matrix (Q4197) (collectively "services at issue"), provided to four (4) beneficiaries across thirty-five (35) claims between **September 2, 2020, and September 8, 2021** ("dates of service"). At initial determination, the Medicare Administrative Contractor (MAC) allowed payment for the services at issue. However, on November 23, 2021, SafeGuard Services LLC, the Centers for Medicare and Medicaid Services (CMS) Unified Program Integrity

[1] This case initially involved 38 claims. But three claims for services provided to H.O. on November 20, 2020, December 23, 2020, and January 7, 2021, are not at issue here. None of the MAC redeterminations adjudicated these three claims. File 27, pp. 4-5, 451-507. The Appellant did not request reconsideration – and the QIC did not adjudicate – these three dates of service. *Compare* File 1, p. 7 (Request for Hearing) *with* File 3, p. 12 (Request for Reconsideration) *and* File 5, p. 14 (Reconsideration). In other words, there is no appealable action regarding these three dates of service. *See* 42 C.F.R. § 405.1002.

Contractor (UPIC), informed the Appellant of its intent to reopen the claims for good cause based on detailed data revealing the questionable billing of high amounts of skin substitute dressings relative to peer norms. File 31, pp. 14-18. On February 23, 2022, after reviewing the Appellant's submitted medical records, the UPIC revealed its post-payment review resulted in all claims (38 at the time) 100% denied because the documentation submitted was insufficient to support medical necessity for the services billed. File 3, pp. 32-38. On April 4, 2022, the MAC issued an overpayment demand letter to the Appellant detailing the identified overpayments totaling **$345,533.46**. File 29, pp. 35-40. The Appellant filed an appeal via its appointed representative, Dominic DeLaurentis, Esq. File 27, pp. 512-18.

On September 14-15, 2022, the MAC issued unfavorable decisions on redetermination upholding the identified overpayments. File 27, pp. 9-499. The Appellant filed a request for reconsideration. File 3, pp. 4-12. On May 16, 2023, the Qualified Independent Contractor (QIC) issued an unfavorable decision on reconsideration upholding the overpayment because documentation was insufficient to support Medicare coverage criteria per the requirements of Local Coverage Determination (LCD) L35041. File 5.

On April 2, 2024, OMHA received the Appellant's timely request for an Administrative Law Judge (ALJ) hearing.[2] File 1, File 17. Pursuant to proper notice, a telephonic hearing was held on June 12, 2024. Files 9, 21, 25. Mr. DeLaurentis appeared as the Appellant's appointed representative. File 9 at 2:00. Marshall Cooper, DPM, a podiatric surgeon employed by the Appellant, provided testimony. *See* File 29, pp. 6-7, File 32, p. 426. Frank Tursi, DPM, and Michael Deml, RN, also attended and provided testimony.[3] *See* File 9 at 3:00; File 20, p. 3; File 32, pp. 436-39. No individuals appeared on behalf of the UPIC, MAC, or QIC. File 9 at 3:30.

ISSUES

The primary issue is whether Appellant received an overpayment for the services at issue provided to the beneficiaries during the dates of service. That issue includes whether the services satisfied Medicare's coverage criteria for payment. If not, there is a further issue whether the Appellant is at fault in causing the overpayment.

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[2] Although the QIC issued its reconsideration decision on May 16, 2023, the Appellant provided evidence of an actual receipt date of February 20, 2024 (more than nine months after the date of the notice). *See* File 1, p. 2; File 5, p. 1; File 13, pp. 1-16. In its request for hearing, the Appellant explained it followed up with the QIC for months in writing and via telephone calls requesting a reconsideration decision. File 1, p. 2. The Appellant provided contemporaneous correspondence from the QIC both acknowledging the reconsideration request filed March 17, 2023, and denying any record of such request on January 15, 2024. File 2, File 13. While the source of this confusion is unclear, it was likely compounded by duplicate requests for reconsideration (1-12532805127 & 1-12532805207). File 2, pp. 13-17, File 8.

Ultimately, the request for hearing – filed April 2, 2024 – is within 60 calendar days of the actual reconsideration receipt date of February 20, 2024. File 1, pp. 37-39. In other words, a good cause determination is unnecessary because the request is not late. Rather, this evidence (a copy of the reconsideration notice with the Appellant's date stamp reading "Feb 20 2024") serves to rebut the presumption that the reconsideration was received five calendar days after the date of the notice. 42 C.F.R. §§ 405.1002, 405.1014(e).

[3] At the hearing, Mr. DeLaurentis qualified Dr. Cooper as a wound care specialist who performed the services at issue. File 9 at 5:30–8:00, File 29, pp. 6-7. Dr. Cooper summarized the process of skin substitutes as it relates to wound healing. File 9 at 16:30. Mr. DeLaurentis then qualified Dr. Tursi, a podiatric surgeon, as a foot and ankle wound care specialist, who recommended Medicare coverage for the services at issue as medically necessary. *See* File 9 at 8:30, File 32, pp. 428-38. Finally, Mr. DeLaurentis qualified Mr. Deml as a Medicare compliance specialist, who contended the services at issue were medically reasonable and necessary as documented in the record. File 9 at 11:20.

LAW & POLICY

Medicare Part B covers "medical and other health services" furnished by a provider of services or by others under arrangement with the provider of services. *See* Act § 1832(a)(2). Pursuant to Section 1862(a)(1)(A) of the Social Security Act (Act), Medicare only covers items and services that are medically reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the function of a malformed body member. *See also* Centers for Medicare & Medicaid Services (CMS) *Internet-Only Manual, Pub. 100-02*, Medicare Benefit Policy Manual (MBPM), Ch. 16, § 20, *and* 42 C.F.R. 411.15(k)(1). Section 1833(e) of the Act precludes payment to any provider of services unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider." *See also* 42 C.F.R. § 424.5(a)(6).

CMS and its contractors issue program guidance in the form of manuals, guidelines, Local Coverage Determinations (LCDs) and Local Coverage Articles (LCAs). The MAC for this jurisdiction issued LCD **L35041** (*v113*, effective Sept. 26, 2019) and LCA **A54117** (*v86*, effective August 13, 2020) regarding Application of Bioengineered Skin Substitutes to Lower Extremity Chronic Non-Healing Wounds. This states, in part:

> **History/Background and/or General Information:**
> This document addresses the management of chronic non-healing wounds of skin deficits of the lower extremities with the goal of wound and skin closure when standard or conservative measures have failed. While lower extremity ulcers have numerous causes, over 90% of the lesions are related to venous stasis disease and diabetic neuropathy. Therefore, the focus of this policy is the application of bioengineered skin substitute material to diabetic foot ulcers (DFUs) and venous leg ulcers (VLUs) of the lower extremities and the reasonable and necessary threshold for utilization of skin substitutes. Particular emphasis is placed on the indications for application of bioengineered skin substitute material.
>
> Medicare coverage for wound care on a continuing basis, for a single wound, in an individual patient is contingent upon evidence documented in the patient's medical record that the wound is improving in response to the wound care being provided. Since it is neither reasonable nor medically necessary to continue a given type of wound care in the absence of wound improvement, it is expected that the wounds response to treatment will be documented in the medical record at least once every 30 days for each episode of wound treatment and made available to the contractor upon request.
>
> **Documentation of response** requires measurements of the initial ulcer, measurements at the completion of at least four weeks of appropriate wound care and measurements immediately prior to placement and with each subsequent placement of the bioengineered skin substitute or cellular or tissue-based product.
>
> **Covered Indications:**
> Chronic Wounds are defined as wounds that do not respond to standard wound treatment for at least a 30-day period during organized comprehensive conservative therapy. For all wounds, documentation, and a comprehensive treatment plan, is required before initiation of a specialized wound therapy product.

A **Failed Response** is defined as an ulcer or skin deficit that has failed to respond to documented appropriate wound-care measures, has increased in size or depth, or has not changed in baseline size or depth and has no indication that improvement is likely (such as granulation, epithelialization or progress towards closing).

Medicare covers application of skin substitutes to ulcers or wounds with **Failed Response** that are:

- Partial- or full-thickness ulcers, not involving tendon, muscle, joint capsule or exhibiting exposed bone or sinus tracts, with a clean granular base;
- Skin deficit at least 1.0 square centimeter (cm) in size;
- Clean and free of necrotic debris or exudate;
- Have adequate circulation/oxygenation to support tissue growth/wound healing as evidenced by physical examination (e.g., Ankle-Brachial Index [ABI] of no less than 0.60, toe pressure greater than 30 millimeters of mercury [mmHg]);
- For diabetic foot ulcers, the patient's medical record reflects a diagnosis of Type 1 or Type 2 Diabetes and also reflects medical management for this condition.

Wound healing is impaired by the systemic use of tobacco. Therefore, ideally patients who have smoked will have ceased smoking or have refrained from systemic tobacco intake for at least 4 weeks during conservative wound care and prior to planned bioengineered skin replacement therapy.

Documentation (in the pre-service record) specifically addressing circumstances as to why the wound has failed to respond to standard wound care treatment of greater than 4 weeks and must reference specific interventions that have failed. Such record should include updated medication history, review of pertinent medical problems that may have occurred since the previous wound evaluation, and explanation of the planned skin replacement surgery with choice of skin substitute graft product. The procedure risks and complications should also be reviewed and documented. Documentation of smoking cessation counseling and cessation measures prescribed, if applicable, must also be documented in the patient's record.

Application of a skin substitute graft for lower extremity chronic will be covered when the following conditions are met for the individual patient:

- Presence of neuropathic diabetic foot ulcer(s) having failed to respond to documented conservative wound-care measures of greater than four weeks, during which the patient is compliant with recommendations and without evidence of underlying osteomyelitis or nidus of infection.

- Presence of a venous stasis ulcer for at least 3 months but unresponsive to appropriate wound care for at least 30 days with documented compliance.

- Presence of a full thickness skin loss ulcer that is the result of abscess, injury or trauma that has failed to respond to appropriate control of infection, foreign body, tumor resection, or other disease process for a period of 4 weeks or longer.

Limitations:
The following are considered not reasonable and necessary and therefore will be denied:

- Partial thickness loss with the retention of epithelial appendages is not a candidate for grafting or replacement, as epithelium will repopulate the deficit from the appendages, negating the benefit of overgrafting.

- Skin substitute grafts will be allowed for the episode of wound care in compliance with FDA guidelines for the specific product (see utilization guidelines) not to exceed 10 applications or treatments. In situations where more than one specific product is used, it is expected that the number of applications or treatments will still not exceed 10.

- Simultaneous use of more than one product for the episode of wound is not covered. Product change within the episode of wound is allowed, not to exceed the 10-application limit per wound per 12 week period of care.

- Treatment of any chronic skin wound will typically last no more than twelve (12) weeks.

- Repeat or alternative applications of skin substitute grafts are not considered medically reasonable and necessary when a previous full course of applications was unsuccessful. Unsuccessful treatment is defined as increase in size or depth of an ulcer or no change in baseline size or depth and no sign of improvement or indication that improvement is likely (such as granulation, epithelialization or progress towards closing) for a period of 4 weeks past start of therapy.

- Retreatment of healed ulcers, those showing greater than 75% size reduction and smaller than 0.5 square cm, is not considered medically reasonable and necessary.

- Skin substitute grafts are contraindicated and are not considered reasonable and necessary in patients with inadequate control of underlying conditions or exacerbating factors (e.g., uncontrolled diabetes, active infection, and active Charcot arthropathy of the ulcer extremity, vasculitis or continued tobacco smoking without physician attempt to affect smoking cessation).

- Re-treatment within one (1) year of any given course of skin substitute treatment for a venous stasis ulcer or (diabetic) neuropathic foot ulcer is considered treatment failure and does not meet reasonable and necessary criteria for re-treatment of that ulcer with a skin substitute procedure.

Documentation Requirements:

- All documentation must be maintained in the patient's medical record and made available to the contractor upon request.
- A description of the wound(s) must be documented at baseline (prior to beginning conservative treatment) relative to size, location, stage, duration, and presence of infection, in addition to the type of treatment given and response.
- Documentation of smoking history, and that the patient has received counseling on the effects of smoking on surgical outcomes and treatment for smoking cessation (if applicable) as well as outcome of counselling must be in the medical record.
- The amount of utilized and wasted skin substitute must be clearly documented in the procedure note with the following minimum information: Date, time and location of ulcer(s) treated; Name of skin substitute and how product supplied; Approximate amount of product unit used; Approximate amount of product unit discarded; Reason for the wastage; Manufacturer's serial/lot/batch or other unit identification number of graft material.
- [The MAC] expects that where multiple sizes of a specific product are available, the size that best fits the wound with the least amount of wastage will be utilized.
- [W]hen billing for Part B drugs and biologicals ... the use of the JW modifier to identify unused drugs or biologicals from single use vials or single use packages that are appropriately discarded is required. The discarded amount shall be billed on a separate claim line using the JW modifier. Providers are required to document the discarded drug or biological in the patient's medical record.

FINDINGS OF FACT AND ANALYSIS

The principal issue on appeal is whether the Appellant received an overpayment for the services at issue provided to the beneficiaries during the dates of service. That issue includes whether such services satisfied Medicare's coverage criteria for payment under Medicare Part B. The UPIC, MAC, and QIC denied Medicare coverage for the services at issue because documentation failed to support the need for skin substitute applications. Specifically, (1) documentation was limited and non-specific to support a failure to respond to standard wound care, conservative treatment for at least a 30-day period, or the wound size at baseline and type of treatment given and response; (2) the record did not support smoking cessation counseling or describe cessation measures prescribed; (3) documentation was insufficient regarding the amount of product discarded and reason for wastage; and/or (4) documentation did not support that the diabetic patients were under the care of a physician for treatment. File 3, pp. 32-38; File 5, p. 10; File 31, pp. 165-69; File 32. On appeal, the Appellant argued the services at issue were medically reasonable and necessary and supported by information in the record. File 9; File 29, pp. 4-20; File 32, pp. 1-27, 428-34.

No.	Initials	Dates of Service	Procedure Codes	Claims	ALJ Disposition
1	E.A.	07/09/21 – 08/27/21	15275, Q4197	6	Partially Favorable

The record shows the Beneficiary, a 65-year-old male, initially consulted with Dr. Cooper on April 2, 2021, for a wound measuring 15 x 4.1 x 0.3 cm located on the posterior aspect of the right plantar foot/posterior leg. File 22, pp. 2-13. His past medical history included hypothyroidism and hypertension. He was a current smoker. Dr. Cooper performed an ankle-brachial index (ABI) to the lower extremities, which measured 0.9 (indicating mild disease). Objective examination of the wound revealed clear drainage and no osteomyelitis. Dr. Cooper debrided the wound and applied lidocaine gel and Silvadene gauze. The diagnoses included right heel pressure ulcer (L89.613) and diabetes mellitus (E11.621). The plan was to redress the wound daily with ointment, be non-weight-bearing (NWB), and return in two weeks for x-ray and follow-up. *Id.* at 10. A progress note dated May 21, 2021, listed the wound measuring 15.1 x 4.1 x 0.3cm. *Id.* at 13. Dr. Cooper again cleaned and debrided the wound. He advised the Beneficiary against smoking.

The Beneficiary presented to the Appellant approximately every 1-2 weeks during the dates of service for PuraPly XT applications to the wound on the right lower extremity (RLE). *Id.* at 10-25. For example, on July 9, 2021, the Beneficiary followed-up with Dr. Cooper for treatment on the open wound ulcer, citing local wound debridement, surgical intervention, and IV oral antibiotics earlier in the year. *Id.* at 14. The wound measured 12 x 2.2 x 0.6cm with a granular base and no infection. A Semmes Weinstein monofilament test of the right leg was diminished. Dr. Cooper assessed diabetic mellitus with neuropathy (E10.610) and right heel stage III pressure ulcer. The wound was debrided under aseptic technique to granular tissue before applying a PuraPly 5cm x 5cm graft. He was again advised against smoking. Approximately two weeks later on July 24, 2021, the Beneficiary received another PuraPly graft application. The diagnoses included unspecified open wound of the right lower leg (S81.801) measuring 11 x 1.1 x 0.4cm. *Id.* at 16. Dr. Cooper advised the Beneficiary to use a wheelchair and return in one week. On each occasion in July 2021, the Appellant billed 54 units of Q4197.

On August 6 and August 13, 2021, the Beneficiary returned for PuraPly applications to the RLE wound measuring 10.3 x 1.5 x 0.8cm and 10 x 1.1 x 0.8cm, respectively. *Id.* at 18-21. The base of the ulcer was granular with no erythema or infection. On each occasion, Dr. Cooper cleaned and debrided the wound before applying a fenestrated 4.9 x 4.9cm graft. Dr. Cooper indicated the wound was significantly improved with grafting. *Id.* at 18. On August 20 and August 27, 2021, Dr. Cooper again applied 4.9cm x 4.9cm PuraPly grafts. *Id.* at 22-25. The wound measured 7 x 0.8 x 0.8cm and 5 x 0.6 x 0.6cm, respectively. On each occasion in August 2021, the Appellant billed 25 units of Q4197.

At the hearing, Dr. Cooper provided testimony explaining he had seen the Beneficiary on at least two occasions prior to beginning treatment with the grafts. Dr. Cooper testified the Beneficiary had undergone numerous debridement sessions. He had advised the Beneficiary to stop smoking. Dr. Cooper testified the size of this wound was quite large, measuring approximately 25^2cm. He initiated graft treatment on July 9, 2021, with demonstrated improvement in the record. He testified he referred the Beneficiary to a smoking cessation program. File 9 at 14:00-20:00.

Dr. Tursi then testified he reviewed the relevant LCD and individual Medicare rules, and the documentation in the record supports the services at issue as medically reasonable and necessary. The reference to diabetes in the record was unclear. Dr. Tursi noted the wound had been present

for more than one month and the non-healing ulcer failed conservative treatment. Regarding the measurements, Dr. Tursi testified the grafts were pulled to fit the wounds without waste. Finally, Dr. Tursi testified regarding supply chains limitations on account of Covid-19 during the dates of service. *Id.* at 21:00-28:00. Mr. Demi then testified the coding employed by Dr. Cooper was consistent with Medicare requirements. He argued the amount of product billed was consistent with the sizing of the wound based on the limited size available and there was no excess wastage since the edges of the graft are folded in the wound. *Id.* at 29:00-35:00, File 3, pp. 252-57, File 31, pp. 253-54.

After a thorough review of the record, I find the testimony of Dr. Cooper, Dr. Tursi, and Mr. Demi, persuasive. The record includes adequate medical documentation supporting medical necessity for the services at issue. The applicable LCD and LCA explain that application of a skin substitute graft to lower extremity non-healing wounds will be covered when, in part, the wound fails to respond to 30-days documented conservative or standard wound care measures, such as a comprehensive patient assessment and implemented treatment plan (debridement, pressure relief, infection control) and review of ABI. A description of the wound must be documented at baseline (prior to beginning conservative wound care measures) with documented response.

The record here supports the Beneficiary's history of non-healing right foot wound despite debridement, surgical intervention, Silvadene cream, and IV antibiotics in the months leading up to the dates of service. The wound did not respond to these conservative measures. There is a complete baseline description of the wound with measurements (15 x 4 x 0.3cm) in April-May 2021. Progress notes confirmed no infection/erythema, ulcer base was granular, and no bone/muscle/tendon involvement. Dr. Cooper performed ABI testing confirming 0.90 (adequate circulation). He advised the Beneficiary to quit smoking and testified regarding referral to smoking cessation program. Contrary to the rationale provided by the Medicare contractors, the medical record supports the Beneficiary's failed response to conservative treatment via measurements of the initial ulcer, measurements at the completion of at least four weeks of conservative wound care, and measurements immediately prior to placement of the skin substitute graft (12 x 2.2 x 0.6cm).

For example, the record leading up to the first date of service explains the Beneficiary was non-weight-bearing, had been prescribed Silvadene cream, and undergone serial debridement for two months, which support the failed conservative measures. According to A54117, the medical record must clearly show that the criteria listed in the LCD has been met, as well as the appropriate diagnosis and response to treatment. Here, the record includes progress notes detailing the wound measurements and corroborating the non-healing wound. During the dates of service in July-Aug 2021, the wound decreased from 12 x 2.2 x 0.6cm to 5 x 0.6 x 0.6cm, as Dr. Cooper noted the significant improvement with grafting.

While the record includes a single reference to diabetes, it does not appear the Beneficiary was formally diagnosed, nor did he self-report any diabetic history. File 9 at 22:00, File 22, p. 4. Total amount of treatments did not exceed the 10-application limit per 12-week period of care during the dates of service. I also note the persuasive testimony of Dr. Tursi and Mr. Demi explaining no product was discarded or wasted (as the edges of the matrix are folded into the wound).

However, I agree with the Medicare Contractors' analysis regarding the graft size application sizing discrepancy in the July 2021 chart notes, lot stickers, and procedure record. *See also* File 31, pp. 381-82. For example, on all four dates of service in August 2021, the EHR system

documentation, lot sticker, and chart notes consistently reflect 25 units of Q4197 (5 x 5cm graft). However, the chart notes associated with the two dates of service in July 2021 detail the application of a 5 x 5cm graft, but the lot stickers cite 6 x 9cm, and the billing record lists 54 units of Q4197. *See* File 31, pp. 20-21, 32-33. In other words, the true size of the grafts applied on July 9, 2021, and July 24, 2021, is unclear. I note the RLE wound measured 26.4 sq cm and 12.1 sq cm, on each date of service, respectively.

Ultimately, the plan of care within the chart notes contemporaneous to the subjective/objective findings, assessment, and procedure note, explicitly describes the application of: "A puraply graft 5cm x 5cm" on two dates of service in July 2021. Section 1833(e) of the Act precludes payment to any provider of services unless there has been furnished such information as may be necessary in order to determine the amounts due such provider. *See also* 42 C.F.R. § 424.5(a)(6). The Appellant has not done so here. For this reason, the preponderance of evidence supports Medicare reimbursement for **25 units of Q4197 on July 9, 2021 and July 24, 2021** (rather than 54 units). *See* Act § 1833(e). While I appreciate the Appellant's testimony regarding supply chain issues due to Covid-19, this does not explain the discrepancy between the chart notes, lot stickers, and billing documents regarding the size of product applied. *See also* File 27, pp. 7, 21.

For the reasons discussed above, the services at issue are covered and payable by Medicare, as outlined in **Attachment B.**

No.	Initials	Dates of Service	Procedure Codes	Claims	ALJ Disposition
2	J.D.	09/02/20 – 03/17/21	15275, Q4159, Q4197	9	Favorable

The record shows the Beneficiary, a 66-year-old female, initially presented to the Appellant's facility on June 17, 2020, complaining of a mid-arch ulcer on her left foot the previous few months. File 12, p 2. Dr. Cooper listed the left plantar foot wound measuring 4.6 x 4.5 x 0.5cm, as well as a new ulcer on the fourth toe of the left foot measuring 0.5 x 0.5 x 0.5cm, with bone exposure. ABI testing was normal. Dr. Cooper debrided both wounds before dressing with sterilize gauze and applying gentamicin cream.

The Beneficiary returned approximately ten weeks later, on September 2, 2020. File 12, pp. 4-10, File 31, pp. 47-53. She listed a past medical history including heart disease, high cholesterol, and diabetes. She had never smoked. The Beneficiary checked boxes on the intake form indicating previous surgical procedures on the foot. File 31, p. 48. Dr. Cooper examined the left foot ulcer and noted it had not improved despite previous treatments including debridement, topical medications, orthotic inserts, and multiple x-rays. The wound measured 4.5 x 4.5 x 0.5cm. An x-ray confirmed no osteomyelitis. Another ulcer on the fifth toe of the left foot measured 0.2 x 0.2 x 0.2cm. File 12, p. 9. Dr. Cooper washed/dressed and debrided both wounds before applying a 2.5 x 2.5cm Affinity graft to the mid-arch ulcer. The plan was to apply gentamicin cream and follow-up in one week. The Appellant billed Medicare, in part, for seven units of Q4159. File 31, pp. 51-52. Dr. Cooper assessed diabetic mellitus with foot ulcer (E11.621).

Approximately three months later, on December 16, 2020, the Beneficiary returned to the Appellant for treatment on the left foot ulcer. Dr. Cooper stated the short supply of Affinity had been replaced with PuraPly. The wound measured 4.1 x 4.1 x 0.4cm. File 31, pp. 54-55. The chart note describes the wound as "Wagner 3" but also states no erythema, cellulitis, or infection. Dr. Cooper states, "Will consider sx if no [sic] resolve have talked to her about this for the mid tarsal. First am going to rapply [sic] graft for midtarsal and wait and see the results." File 31, p.

54. Dr. Cooper applied a 5 x 5 cm PuraPly graft to the wound and re-listed the same diagnoses (diabetes and non-pressure chronic ulcer of the left foot).

The Beneficiary presented to the Appellant on three occasions in January 2021. File 31, pp. 57-65. On January 6, 2021, the ulcer (listed as a "diabetic wound") on the mid-plantar arch of the left foot measured 4.1 x 4.0 x 0.4cm. File 31, p. 57. The note described the base of the ulcer as granular with no erythema or cellulitis. Dr. Cooper cleaned and debrided the wound before placing a 2.5 x 2.5cm Affinity amniotic membrane covering. The chart note indicates her A1c ranges to 7. The note concludes, "have explained to her because she went on vacation without telling us in September graft sequence and healing was delayed." File 31, p. 57. On January 20, 2021, and January 27, 2021, the Beneficiary returned for additional wound treatment. On both occasions, the chart notes describe Dr. Cooper debriding and cleaning the left foot wound before applying a 2.5 x 2.5 cm Affinity wound covering. File 31, pp. 60, 63. The wound measured 3.8 x 3.7 x 0.4cm, and 3.7 x 3.7 x 0.4cm, respectively.

The Appellant performed additional Affinity applications to the left foot wound in February 2021. On February 11, 2021, the wound measured 3.8 x 2.9 x 0.3cm. Two weeks later, on February 24, 2021, the wound measured 2.8 x 1.9 x 0.3cm. File 31, p. 69. Dr. Cooper indicated the diabetic ulcer wound showed "continuing improvement with decreased size and healthy granular base tissue." On each occasion, according to the chart notes, Dr. Cooper cleaned/debrided the wound and applied topical ointment. It appears the Appellant utilized two Affinity 2.5 x 2.5 cm wound covering (14 units) on February 11, 2024, and one 2.5 x 2.5cm wound covering (7 units) on February 24, 2021. File 31, pp. 66-71. The listed diagnoses were L89.893 (stage 3 pressure ulcer) and E11.521 (type II diabetes with foot ulcer). File 31, pp. 66-71.

The Beneficiary returned on March 3, 2021, for treatment on the left midtarsal plantar wound. File 31, pp. 72-73. Dr. Cooper noted continued improvement with epithelial tissue and granular tissue, as the wound measured 2.8 x 1.9 x 0.3cm. The chart note denied any cellulitis, infection, or odor. Dr. Cooper debrided and cleaned the wound before applying an Affinity 2.5 x 2.5cm wound covering. File 31, pp. Dr. Cooper advised the Beneficiary against removing the bandages and recommended returning in one week. On March 17, 2021, the Beneficiary returned for wound treatment. Dr. Cooper stated that the Beneficiary went on a month or so vacation after the early applications and he felt progress was delayed until early 2021. File 31, p. 75. The wound measured 2.6 x 1.8 x 0.3cm. Dr. Cooper cleaned and debrided the wound before applying two Affinity 2.5 x 2.5cm wound coverings (14 units) to cover the full tissue area. File 31, pp. 75-77.

At the hearing, Dr. Cooper provided testimony explaining the Beneficiary was a diabetic suffering from a left foot plantar wound. Dr. Cooper stated the Beneficiary was being following by a medical doctor per the physician acknowledgement in the record. File 9 at 48:30, *see also* File 12, p. 27. Dr. Cooper testified he had seen her on 2-3 occasions in the summer of 2020 prior to proceeding with the wound graft applications. Dr. Cooper listed failed conservative treatment including orthotics, debridement, and antibiotic creams, before starting grafting on September 2, 2020. He further explained the graft size was appropriate per the wound measurements, which improved from 4.5 x 4.5cm in September 2020, to 2.6 x 1.8cm in March 2021. He also highlighted that the record includes a note from a "Dr. Mayo" confirming the Beneficiary's treatment for diabetes the previous five years. File 9 at 52:00, File 12, p. 27.

Dr. Tursi then testified he reviewed the record, relevant LCD, and individual Medicare rules, and the documentation in the record supports the services at issue as medically reasonable and necessary. File 9 at 54:30. Dr. Tursi noted multiple months of failed conservative treatment,

diabetes actively managed by a physician, and chart records detailing updated wound size measurements. Dr. Tursi noted the wound size may have stalled a bit while she was on vacation, but when compliant with treatment, the record evidences improvement in wound size and tissue. Mr. Demi then testified the amount of product billed was consistent with the sizing of the wound based on the limited size available and there was no excess wastage. *Id.* at 55:00. Mr. Demi opined the documentation was sufficient to support coverage and payment. *Id.*

After a thorough review of the record, I find the testimony of Dr. Cooper, Dr. Tursi, and Mr. Demi, persuasive. The record includes adequate medical documentation supporting medical necessity for the services at issue. The applicable LCD and LCA explain that application of a skin substitute graft to lower extremity chronic non-healing wounds will be covered when, in part, the wound fails to respond to standard wound care treatment for at least a 30-day period during organized comprehensive conservative therapy. L35041, A54117. Conservative wound care measures must be documented in a comprehensive treatment plan and include debridement, mechanical offloading, infection/edema control, and management of any inciting medical issues. Documentation of response requires measurements of the initial ulcer, measurements at the completion of conservative wound care, and measurements immediately prior to placement of the skin substitute graft. *Id.*

The record details the Beneficiary's history of a chronic non-healing diabetic foot ulcer (DFU) on the sub-mid arch of the left foot. Chart notes in June-July 2020, more than 30-days prior to the dates of service, describe conservative treatment including multiple debridement, gentamicin cream, and orthotic shoes. The wound did not respond to these conservative measures. There is also a complete baseline description of the wound with measurements (4.6 x 4.5 x 0.5cm) in June-July 2020 before/after conservative wound treatment. Progress notes confirmed no infection or erythema, ulcer base was granular, and no bone/muscle/tendon involvement. While a chart note references "Wagner 3", the objective findings and assessment describe no erythema or cellulitis, while x-rays confirmed no osteomyelitis. Dr. Cooper performed ABI testing (normal). A note in the record evidences physician involvement in terms of the Beneficiary's diabetes management. A chart note confirms the Beneficiary's A1c range managed < 7. Dr. Cooper advised the Beneficiary to continue with her primary physician for diabetic care.

Contrary to the rationale provided by the Medicare contractors, the medical record supports the Beneficiary's failed response to conservative treatment via measurements of the initial ulcer, measurements at the completion of at least four weeks conservative treatment, and measurements immediately prior to placement of the skin substitute graft (4.5 x 4.5 x 0.5cm). For example, the record leading up to the first date of service explains the left foot diabetic ulcer had been present for multiple months and treated with topical medications, orthotic inserts, and debridement. The record also includes progress notes detailing the wound measurements and corroborating the non-healing wound. Between September 2020 through January 2021, the wound decreased from 4.5 x 4.5 x 0.5cm to 3.7 x 3.7 x 0.4cm, despite a delay in healing when the Beneficiary went on vacation. After four treatments in February-March 2021, the wound further decreased to 2.6 x 1.8 x 0.3cm. Dr. Cooper examined the wound and confirmed continued improvement with epithelial tissue of the perimeter and reduction in size.

The total amount of treatments also did not exceed the 10-application limit per 12-week period of care during the dates of service. As noted by Dr. Cooper, the wound had made substantial progress by the final date of service, although it had not completely healed because the patient went on a vacation for a month or so in the early applications, which delayed progress. Regarding the UPIC's allegation that the record did not document the amount of product wasted - significantly - only when a portion of a drug or biological is discarded must the record

document the amount wasted and reason for wastage. A5411?. Here, as supported by the testimony of Dr. Tursi and Mr. Demi, no product was discarded or wasted because the edges of the wound matrix were folded into the wound to fill the entire depth and achieve optimal wound healing. In other words, use of the JW modifier would be inappropriate. The record also documents appropriate selection of wound cover sizing in relation to the wound. In fact, the record indicates Dr. Cooper utilized a 6.25 sq cm amniotic membrane on the 20.25 sq cm wound in September 2020, 12.5 sq cm grafts on the 11-14 sq cm wound in January-February 2021, and a 6.25 sq cm covering on the 5.3 sq cm wound in March 2021.

For these reasons, the preponderance of evidence supports Medicare coverage and payment for the services at issue, as outlined in **Attachment B.**

No.	Initials	Dates of Service	Procedure Codes	Claims	ALJ Disposition
3	A.L.	03/10/21 – 09/08/21	15275, Q4159, Q4197	16	Unfavorable

The record shows the Beneficiary, an 80-year-old male, initially presented to the Appellant in March 2019 for an evaluation of a diabetic ulcer on the 1st toe of the left foot. File 30, pp. 2-7. He reported having this problem for 1-2 months and listed prior treatment including debridement, topical wound ointments, and post op shoes. The wound measured 0.5 x 0.5 x 0.5cm with no tunneling, erythema, cellulitis, or infection. He denied any pain. He had never been a smoker. Dr. Cooper cleaned and debrided the wound before dressing with Silvadene cream and instructing the Beneficiary to apply Silvadene daily and avoid wearing sneakers.

Approximately two years later, on March 2, 2021, the Beneficiary returned for evaluation of a diabetic ulcer on the 1st toe of the left foot. File 30, p. 8. The wound measured 1.2 x 1.0 x 0.5cm with no osteomyelitis or infection. Dr. Cooper assessed E11.621 (type 2 diabetes mellitus with foot ulcer) and L89.893 (pressure ulcer stage 3). He debrided the wound and dressed it with gentamicin cream before recommending diabetic shoe inserts and Silvadene cream.

The Beneficiary returned to the Appellant on three more occasions in March 2021. File 30, pp. 9-14. On March 10, 2021, the first date of service, Dr. Cooper assessed the wound and measurements (1.1 x 1 x 0.3cm) before cleaning/debriding and applying a 2.5 x 2.5 cm Affinity wound covering. File 30, p. 9. Although the wound edges had an eschar, it was clean and granular after debridement. A vascular examination revealed weak or diminished dorsalis pedis (DP) and posterior tibial (PT) pulses rated 1/4 bilaterally. There were no ABI test results listed. File 30, p. 9. On March 17, 2021, the wound measured 1 x 1.2 x 0.3cm. On March 25, 2021, the wound measured 0.9 x 0.9 x 0.3cm. On both occasions Dr. Cooper cleaned and debrided the 1st toe left foot wound and applied a 5 x 5cm PuraPly graft. On both dates, the Appellant billed Medicare, in part, for 25 units of Q4197 (10 units associated with modifier JW). File 31, pp. 90-93.

Approximately 1x/week during April-May 2021, the Appellant presented to Dr. Cooper for continued evaluation of the diabetic ulcer. File 30, pp. 15-27. During this time, the wound size decreased from 0.8 x 1.0 x 0.3cm to 0.1 x 0.2 x 0.1 cm. Vascular examinations confirmed diminished DP and PT pulses at 1/4. The base of the ulcer was half granular half necrotic. The second toe medial PIPJ was starting to develop necrotic skin. On each of these seven dates of service, Dr. Cooper cleaned/debrided the wound before applying an Affinity 2.5 x 2.5cm covering. The Appellant billed Medicare for, in part, 7 units (6.25 sq cm) of Q4159, with no JW modifier.

On August 4, 2021, the Beneficiary followed-up with the Appellant for evaluation of the diabetic ulcer. It had healed. File 30, pp. 29-30. However, the Beneficiary reported a new wound on the 1st metatarsal head of the left foot beginning approximately five months prior. The Beneficiary reported conservative treatment of debridement and ointments/dressings. The wound measured 1.1 x 1.1 x 0.3cm with no tunneling or infection. Dr. Cooper cleaned/debrided the wound, applied a 5 x 5cm PuraPly graft, and advised the Beneficiary to return in a week. The diagnoses continued as diabetes with foot ulcer and stage III pressure ulcer. *See* File 30, p. 30.

The Beneficiary returned on August 11, August 18, and August 25, 2021, for continued treatment of the ulcer on the sub 1st metatarsal head of the left foot. File 30, pp. 31-36. During this time, the wound size decreased from 1.1 x 1.1 x 0.3cm to 0.3 x 0.4 x 0.2cm. Examinations revealed a granular base with no necrotic margins or edema. On each occasion, Dr. Cooper cleaned and debrided the wound before applying a 5 x 5cm PuraPly graft. The Appellant billed Medicare for, in part, 25 units of Q4197 (21 units with modifier JW) on each of the four dates of service in August 2021. *See infra* note 4.

On September 1 and September 8, 2021, the Beneficiary returned for wound treatment. Dr. Cooper stated the ulcer on the sub 1st metatarsal head was improving. File 30, pp. 37-40. The wound measured 0.2 x 0.2 x 0.2cm. Dr. Cooper cleaned/debrided the wound and applied a 4.9 x 4.9cm PuraPly graft. Vascular examination showed diminished pulses rated 1/4. Dr. Cooper recommended new diabetic shoes. A note e-signed by Dr. Christian Ellison, M.D., states that the Beneficiary was under physician care for diabetes management in 2020-21. File 30, p. 43.

A letter from Dr. Cooper dated December 21, 2021, indicates modifier "JW Graft Waste" was listed on eight dates of service.[4] File 31, p. 87, *see also* File 31 at 88-133. Dr. Cooper explained that waste occurred due to the product being the smallest size manufactured by the company. The PuraPly product was chosen due to the thick Matrix and Antimicrobial properties to facilitate wound healing. File 31, p. 87.

At the hearing, Dr. Cooper provided testimony stating he saw the Beneficiary on two occasions prior to the dates of service and provided debridement, Silvadene cream, and lidocaine gel. File 9 at 57:00. Dr. Cooper also highlighted a document in the record from Dr. Ellison indicating physician involvement for diabetic care during the dates of service. *See* File 30, p. 43. Dr. Cooper then explained that this Beneficiary was the only individual of the four with documented product waste. File 9 at 58:00. He noted the record also includes documentation of the wastage with an explanation that size selected was the smallest size manufactured by the company. File 9 at 59:00, File 30, p. 42. Dr. Tursi then testified this Beneficiary underwent a month of conservative care including post op shoes, ointments, and dressing changes. File 9 at 1:00:00. He contended the size was appropriate, vascular status was sufficient, and diabetes was managed by a physician. Mr. Demi then testified that in his opinion the services at issue were medically necessary during the dates of service in question. File 9 at 1:02:00.

After a thorough review of the record, the undersigned disagrees because the Appellant failed to submit adequate medical documentation supporting medical necessity for the services at issue. The applicable LCD and LCA explain that application of a skin substitute graft to lower extremity chronic non-healing wounds will be covered when, in part, the wound fails to respond to documented conservative wound-care measures of greater than four weeks, during which the

[4] March 17, March 25, August 4, August 11, August 18, August 25, September 1, and September 9, 2021. Each of these claims included a JW modifier documenting amount of Q4197 wasted. *See* File 31, pp. 90 (10 units); 93 (10 units); 117 (21 units); 120 (21 units); 123 (21 units); 126 (21 units); 129 (21 units); and 132 (21 units).

patient is compliant with treatment. L35041, A54117. Conservative wound care measures must be documented in a comprehensive treatment plan and include debridement, mechanical offloading, infection and edema control, and management of inciting medical issues.

Documentation of response requires measurements of the initial ulcer, measurements at the completion of at least four weeks of conservative wound care measures, and measurements immediately prior to placement of the skin substitute graft. The pre-service record must specifically address circumstances as to why the wound has failed to respond to standard wound care treatment and must reference specific interventions that have failed based on the prior wound evaluation. *Id.*

It is first important to note that the dates of service here straddle two distinct diabetic ulcers. Treatment between March 10, 2021, and May 27, 2021, involved the wound located on the first toe of the left foot ("Wound #1"). When that wound healed, treatment between August 4, 2021, and September 8, 2021, involved the wound on the left foot sub 1st metatarsal head ("Wound #2").

Regarding Wound #1, while the record includes two chart notes from Dr. Cooper prior to the dates of service, the first is dated May 2, 2019 – nearly two years prior, and the second is dated March 2, 2021 – only one week prior. The March 2, 2021, note indicates the Beneficiary presented for evaluation of a diabetic ulcer "for the last few months". The wound measured 1.2 x 1.0 x 0.5cm. Dr. Cooper debrided and applied lidocaine gel. On the first date of service the following week, March 10, 2021, the wound had slightly decreased in size to 1.1 x 1.0 x 0.3cm. In other words, the record evidences only one week of conservative treatment contemporaneous to the dates of service, and rather than supporting a failed response, such evidence indicates the brief measure of conservative care indeed advanced wound healing progress.

Regarding Wound #2, the record shows the Beneficiary returned to the Appellant on August 4, 2021, complaining of this new wound present for approximately five weeks. The wound measured 1.1 x 1.1 x 0.3cm. Dr. Cooper applied a 5 x 5cm PuraPlay graft to the new wound that very day. While the chart note suggests the wound had been treated with debridement and ointments/dressings, there is no documentation in the record detailing such conservative treatment. Contrary to the hearing testimony, the record does not detail failed conservative treatments contemporaneous to the dates of service. Indeed, the record lacks any medical evidence whatsoever regarding the status of Wound #2 in the four weeks leading up to these dates of service. There is no Documentation of Response or wound measurements immediately prior to beginning conservative treatment. Ultimately, as highlighted by the MAC and QIC, the medical record does not document the Beneficiary's response to conservative treatment via measurements at *baseline* (prior to beginning conservative treatment) and at the *completion of at least four weeks of conservative wound care*. Chart notes also do not *specifically address* the circumstances as to why the wounds failed to respond to standard wound care treatment. L35041.

I also note that Medicare covers application of skin substitutes where the skin deficit is at least 1.0 sq cm in size, clean and free of necrotic debris or exudate, and with adequate circulation to support tissue growth and wound healing. L35041. Here, Wound #1 and Wound #2 measured less than 1.0 sq cm in size on 13 of the 16 dates of service.[5] The wounds were also regularly

[5] Wound #1 measured greater than 1 sq cm on the first and second dates of service (1.1 sq cm and 1.2 sq cm), as did Wound #2 on its first date of service (1.21 sq cm). File 30, pp. 9-11, 29. On all other dates of service, the wounds were less than 1.0 sq cm in size. File 30, pp. 13-40. For example, at its largest in April-May 2021, Wound #1 measured 0.8 sq cm (0.8 x 1.0cm). The LCD explains that the application of skin substitute is distinguished according to the wound characteristics and surface area – which differentiates wound size from wound depth. The

described as "Wagner 3", which is indicative of a deep abscess, osteomyelitis, or joint sepsis. The record did not include any ultrasounds or arterial study results documenting adequate circulation/oxygenation to support tissue growth and wound healing. Instead, vascular examinations on each date of service revealed weak or diminished dorsalis pedis and posterior tibial pulses at 1/4 bilaterally, indicative of poor circulation. While a one-sentence note from Dr. Ellison indicates the Beneficiary was under the care of a physician for diabetes in 2020-21, the record does not otherwise include any A1c measurements or provide any details supporting adequate control of this underlying condition.

Finally, after a thorough review of the record, I agree with the Medicare Contractors that documentation does not support the smallest size with the least amount of wastage was utilized, as required by A54117. When a portion of a drug/biological is discarded, the medical record must clearly document the amount administered, amount wasted, and the reason for the wastage. A54117. On 8 of the 16 dates of service here, the Appellant included the "JW" modifier identifying unused product. *See* File 30, p. 42, *supra* note 4. Dr. Cooper stated that waste occurred due to product used being the smallest size manufactured by the company. He noted this product was chosen due to the thick matrix and antimicrobial properties to facilitate wound healing. *Id.*

But again, Wound #1 measured less than 1 sq cm on 8/10 relevant dates of service in March-May 2021, while the Appellant continued utilizing 25 sq cm PuraPly grafts or 6.25 sq cm Affinity allografts. The claims associated with 8/10 of these dates of service did not include a JW modifier, suggesting there was no wastage. Yet the graft size in proportion to the wound size was many multiples higher. For example, on April 21, 2021, the wound measured 0.15 sq cm (0.3 x 0.5cm), with a depth of only 0.2cm, but the Appellant selected a 6.25 sq cm allograft (40x the size). File 30, p. 42. Regarding Wound #2, there are some discrepancies in the record in terms of references to meters vs. centimeters. For example, the chart note dated August 11, 2021, appears to list the wound length as ".8m" – which would mean this big toe wound measured 80cm in length. The accompanying photos in the record certainly do not support a wound this size. File 30, pp. 4-6. Dr. Tursi addresses this typographical error in his submitted spreadsheet, clarifying the wound length as "0.8 cm". File 26, p. 9, File 32, p. 20.

Similar to the first wound, Wound #2 measured less than 1 sq cm on 5/6 relevant dates of service in August-September 2021, yet the Appellant continued utilizing 25 sq cm PuraPly grafts. For example, on September 8, 2021, the wound measured 0.04 sq cm (0.2 x 0.2cm), with a depth of only 0.2cm, but the Appellant selected a 25 sq cm graft (600x the size). The Appellant billed Medicare for 25 units of Q4197, but only 4 of the 25 units were utilized (84% wasted per the JW modifier). File 30, p. 39. This buttresses the conclusion of the Medicare contractors that the size selection did not best fit the wound with the least amount of wastage, as required by A54117.

I agree with the conclusion of the Medicare Contractors because the Appellant failed to submit adequate medical documentation supporting medical necessity for the services at issue. For the reasons discussed above, the services at issue are not covered by Medicare, as outlined in **Attachment B.** Act §§ 1833(e) and 1862(a)(1).

LCD consistently references wound measurements via square cm (L x W) rather than cubic cm (L x W x D). L35041. For example, a failed response to conservative treatment is defined as a skin deficit that has increased in size *or depth*, or has not changed in baseline size *or depth*. L35041. Again, the LCD requires that the skin deficit be at least 1.0 square cm in size. For the purposes of this calculation, therefore, "wound size" is measured by multiplying length x width.

No.	Initials	Dates of Service	Procedure Codes	Claims	ALJ Disposition
4	H.O.	01/21/21 – 03/19/21[6]	15277, Q4159	4	Favorable

The record shows the Beneficiary, a 67-year-old male, initially presented to the Appellant in September 2020 with complaints of an infected wound on the left lower extremity (LLE). File 23, pp. 2-7. Dr. Cooper performed an excision of decompression and resection of tissue of the LLE due to necrotizing fasciitis. Once extensive debridement and decompression was performed, the wound was inspected, showing a somewhat granular base with small islands of fatty tissue. Dr. Cooper took wound cultures and sent the Beneficiary to the recovery room in stable condition. The prognosis was extremely guarded. Surgical pathology results the following week confirmed necrosis and dense acute inflammation of the specimen. A follow-up pathology report on September 28, 2020, indicated the presence of fibroadipose tissue with gangrenous necrosis.

On October 2, 2020, Dr. Cooper performed another excision and debridement of the large open wound on the LLE measuring 22 x 20 x 1.0cm. File 23, pp. 8-9. He observed exposed fascia muscle and bone, before performing pulse lavage utilizing normal saline mixed with gentamicin antibiotic irrigation. On October 7, 2020, Dr. Cooper debrided the open wound and noted an improved appearance compared to the last surgical debridement with many islands of granular tissue and capillary returns, despite the exposed bone. File 23, pp. 11-12. Dr. Cooper resected all avascular necrotic islands and curettaged the exposed bone before sending the Beneficiary to the recovery room in stable condition. The Beneficiary returned on November 20, 2020, for another excisional debridement of the LLE wound. File 23, pp. 18-19. The wound had been present for several months and the Beneficiary was non-weight bearing. The Beneficiary also reported applying antibiotic ointments and utilizing post op shoes. The wound measured 16 x 9 x 0.5cm on the lateral foot with a clean granular base. Dr. Cooper diagnosed pyoderma gangrenosum inflammatory disorder (L88) and open wound of the left leg (S81.802), before applying a 6x9 PuraPlay XT wound graft.

The Beneficiary returned to Dr. Cooper on two occasions in December 2020 for follow-up of the LLE wound. File 23, pp. 20-23. He had been surgerized multiple times in the operating room and had been debrided and sterile dressed. X-rays showed no osteomyelitis, although he was on steroids for the pyoderma gangrenosum. Objective assessments on both occasions showed a granular base with no cellulitis, erythema, or bone/tendon exposure. The wound measured 15 x 6.3 x 0.6cm and 14.7 x 7.9 x 0.5cm, respectively. Dr. Cooper debrided the wound and applied a wound graft to promote healthy granular tissue and wound healing. A follow-up chart note dated January 7, 2021, describes the Beneficiary continuing to complain of the open wound on the LLE. File 23, p. 25. There was no purulence, infection, edema, or cellulitis. Margins were granular and the wound measured 14.4 x 6.1 x 0.4cm. Dr. Cooper debrided the wound and applied an Affinity amniotic membrane wound covering.

On January 21, 2021, the first date of service here, the Beneficiary presented to Dr. Cooper for LLE wound treatment. File 23, pp. 26-27. The medical note indicates the Beneficiary was taking prednisone and was non-weight bearing. The wound measured 14 x 5.9 x 0.4cm. Dr. Cooper diagnosed repeat open wound of the left leg (S81.802D) and debrided the wound. The chart note states Dr. Cooper "applied Affinity a fresh placental membrane...28sq cm". File 23, p. 27. On January 28, 2021 (second date of service), the Beneficiary returned for LLE wound treatment. File 23, pp. 28-29. He reported pain rated 1/10. The wound measured 14 x 5.5 x 0.3cm without any evidence of edema, infection, cellulitis, or erythema. There was no tendon/bone

[6] *See supra* note 1.

involvement, and the wound base was granular throughout. Dr. Cooper cleaned and debrided the wound before applying 28 units of Q4159 (Affinity). The Appellant billed 28 units of Q4159. The plan was to return in a week for additional application.

On February 4, 2021 (third date of service), Dr. Cooper again evaluated the Beneficiary's LLE wound. File 23, pp. 30-31. The wound displayed no purulence, infection, or edema. It measured 13.2 x 5.5 x 0.3cm. Dr. Cooper described the wound as healing with improving granular tissue from prior affinity grafts. The diagnosis listed non-pressure ulcer of the left leg (S81.802D). Dr. Cooper debrided and cleaned the wound before applying "four Affinity 2.5 x 2.5 cm for a total of 28sq cm of fresh placental membrane." File 23, p. 30. The Appellant billed 28 units of Q4159.

On the final date of service approximately six weeks later, March 19, 2021, the Beneficiary returned to the Appellant for LLE wound care. File 23, pp. 32-33. He continued taking prednisone 10mg. The wound bed was granular with no tunneling or infection. The wound measured 13 x 5.3 x 0.3cm. Dr. Cooper debrided and cleaned the wound before applying four affinity grafts each measuring 2.5 x 2.5cm.

At the hearing, Dr. Cooper provided testimony explaining he first treated this Beneficiary for necrotizing fasciitis in September 2020. File 9 at 36:30. Dr. Cooper noted this Beneficiary was quite sick, requiring multiple surgeries on the wound prior to the dates of service. Dr. Cooper explained that repeat debridement, while helpful, was insufficient in treating this non-healing wound. He argued that while conservative treatment successfully addressed prior infections causing necrosis, the wound needed further assistance via amniotic grafts, and the services at issue were therefore medically necessary to simulate healing and reduce inflammation. File 9 at 40:00. Due to supply chain issues, according to Dr. Cooper, the Appellant switched between Affinity and PuraPly grafts depending on availability. Dr. Cooper explained there was no waste of the product during the dates of service as evidenced by comparing the product dimensions with the wound size ("the wound comprised the entire side of his leg"). File 9 at 42:00. Dr. Cooper also noted the Beneficiary did not smoke and was not a diabetic. He concluded stating the services at issue were medically reasonable and necessary as evidenced by the reducing wound size.

Dr. Tursi then provided testimony summarizing the two months of failed conservative and surgical treatment prior to the dates of service. File 9 at 43:30. He noted the baseline wound size was massive (144 sq cm) requiring intense intervention to avoid leg amputation. Dr. Tursi clarified the record did not include any medical documentation suggesting the Beneficiary was a diabetic. Mr. Demi then testified that the documentation establishes medical necessity based on Medicare requirements. File 9 at 46:30.

After a thorough review of the record, I find the testimony of Dr. Cooper, Dr. Tursi, and Mr. Demi persuasive, as the record includes adequate medical documentation supporting medical necessity for the services at issue. The applicable LCD and LCA explain that application of a skin substitute graft to lower extremity non-healing wounds will be covered when, in part, the wound fails to respond to 30-days documented conservative or standard wound care measures, such as a comprehensive patient assessment and implemented treatment plan (debridement, pressure relief, infection control). A description of the wound must be documented at baseline (prior to beginning conservative wound care measures) with documented response.

The record here supports the Beneficiary's history of a large non-healing LLE wound despite repeat debridement, surgical intervention, ointment/cream, and IV antibiotics in the months leading up to the dates of service. The wound did not respond to these conservative measures.

The record also includes a complete description of the wound with initial measurements in Oct 2020 (22 x 20cm) and measurements at the completion of conservative treatment in Nov 2020 (25 x 25cm). Although necrotizing fasciitis was present in October 2020, the excisional debridement and antibiotics were effective, as progress notes in January 2021 describe no infection, cellulitis, or erythema. Again, medical documentation during the dates of service repeatedly list a granular ulcer base with no bone/muscle/tendon involvement. Contrary to the rationale provided by the Medicare contractors, the medical record supports the Beneficiary's failed response to conservative treatment via measurements of the initial ulcer and at the completion of conservative treatment in October 2020 (20 x 20cm), and measurements immediately prior to first placement of a skin substitute graft in November 2020 (16 x 9 x 0.5cm).

For example, the record leading up to the first date of service explains the Beneficiary was on/off-weight-bearing, taking prednisone, and had undergone serial debridement for two months, supporting failed conservative measures. Although he was diagnosed with wound infections such as necrotizing fasciitis in October 2020, the IV antibiotics and surgical procedures successfully cleared the wound of any infection by the dates of service, as verified by Dr. Cooper. According to A54117, the medical record must clearly show that the criteria listed in the LCD has been met, as well as the appropriate diagnosis and response to treatment. Here, the record includes progress notes detailing the wound measurements and corroborating the non-healing wound. During the dates of service in Jan-March 2021, the wound decreased from 14 x 5.9 x 0.4cm to 13 x 5.3 x 0.3cm (from a size of nearly 25 x 25cm in October 2020). The total amount of treatments did not exceed the 10-application limit per 12-week period of care during the dates of service. I also note the persuasive testimony of Dr. Tursi and Mr. Deml explaining no product was discarded or wasted due to the enormous size of the wound.

The LLE wound averaged 75 sq cm during the dates of service. It appears the Appellant utilized multiple iterations of Q4159 (6.25 sq cm) on each date of service in order to cover the entire surface area.[7] File 27, pp. 451, 465, 479. Chart notes list the application of Affinity fresh placental membrane totaling 28 sq cm. Lot stickers show four 2.5 x 2.5 Affinity allografts, consistent with the product and units billed for each claim on the relevant dates of service.

For the reasons discussed above, the services at issue are covered and payable by Medicare, as outlined in **Attachment B.**

LIABILITY AND OVERPAYMENT

Having concluded Medicare does not cover all claims for all beneficiaries during the dates of service, I must next determine financial responsibility for the non-covered charges. According to Section 1879 of the Act, when Medicare denies coverage of an item or a service as not reasonable and necessary under Section 1862(a)(1)(A), payment nevertheless may be made for the items or services if neither the beneficiary nor the provider knew, and could not reasonably be expected to have known, that the items or services would not be covered or payable by Medicare. Act § 1879.

Here, both the MAC and QIC decided that the Appellant was responsible for the costs of the non-covered charges. File 5, File 29. The Appellant is presumed to have knowledge of the published Medicare regulations, rules, policies, and all other coverage criteria. 42 C.F.R. § 411.406. The record does not contain evidence that rebuts that presumption in this case.

[7] The Appellant also ostensibly supplied multiple products on March 19, 2021, including Q4196 (PuraPly AM), which is not at issue here. *See* File 27, pp. 493-94, File 31, p. 257.

Therefore, the Appellant knew or could have reasonably known that certain services at issue would not be covered, and thus remains responsible for the non-covered charges. With regard to the unfavorable claim lines, there is insufficient evidence in the record that the beneficiaries had been provided sufficient information, such as an Advanced Beneficiary Notice (ABN), to understand and/or accept responsibility for the non-covered costs. Therefore, these beneficiaries are entitled to limitation on liability under Section 1879 of the Act and cannot be billed for the non-covered charges.

Section 1870 of the Act permits a provider/supplier to avoid liability for an overpayment if the such was "without fault" in causing the overpayment. Here, the Appellant accepted payment which it knew or could have been expected to know was incorrect. The Appellant in this had constructive notice of Medicare coverage rules through widely published Medicare regulations and CMS policy manuals. As such, the Appellant is not without fault because it is aware of the billing and documentation requirements for claims submitted to Medicare. Overpayment recovery cannot be waived under Section 1870 of the Act, and the Appellant remains liable for the non-covered charges.

This decision, however, reverses in whole or in part select initial claim determinations used to calculate the overpayment amount. *See* Attachment B. Therefore, the overpayment amount needs to be recalculated and a revised overpayment decision (i.e. demand letter) issued to the Appellant. The Medicare contractor **will take the appropriate action to adjust the overpayment consistent with this decision** and take any further appropriate action as necessary. The Appellant is entitled to a refund of any payments, monies, or amounts previously collected by Medicare in excess of the recalculated overpayment amount.[8]

CONCLUSIONS OF LAW

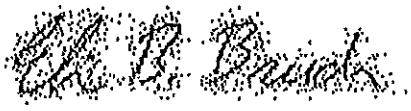
Pursuant to Section 1862(a)(1)(A) of the Act, Medicare covers and pays for the claim lines identified as "Favorable" or "Partially Favorable" within **Attachment B.** All remaining services at issue are not medically reasonable and necessary and therefore not covered for the reasons described above. The beneficiaries are entitled to relief under Section 1879 of the Act and are not liable for such non-covered charges. The Appellant's liability is not limited, and it is also not without fault in causing the overpayment under Section 1870 of the Act.

ORDER

For the reasons discussed above, this decision is **PARTIALLY FAVORABLE.** The Medicare Administrative Contractor is **DIRECTED** to process the claims in accordance with this decision.

[8] Only CMS has the authority to waive or refund interest collected or charged on an overpayment. 42 C.F.R. §§ 405.378(b), 405.378(f)(1); MFMM, Ch. 4, §30.6.

SO ORDERED



ELI BRUCH
Administrative Law Judge

DEPARTMENT OF HEALTH AND HUMAN SERVICES (DHHS) / DEPARTMENTAL APPEALS BOARD Form DAB-101 (12/19)

REQUEST FOR REVIEW OF ADMINISTRATIVE LAW JUDGE (ALJ) MEDICARE DECISION / DISMISSAL

1. APPELLANT (the party requesting review)	2. ALJ APPEAL NUMBER (on the decision or dismissal)
3. BENEFICIARY*	4. MEDICARE NUMBER (Health Insurance Claim Number (HICN) or Medicare Beneficiary Identifier (MBI))*

*If the request involves multiple claims or multiple beneficiaries, attach a list of beneficiaries, Medicare numbers, and any other information to identify all claims being appealed.

5. PROVIDER, PRACTITIONER, OR SUPPLIER	6. SPECIFIC ITEM(S) OR SERVICE(S)

7. Medicare claim type: ☐ Part A ☐ Part B ☐ Part C - Medicare Advantage
☐ Part D - Medicare Prescription Drug Plan ☐ Entitlement/enrollment for Part A or Part B

8. Does this request involve authorization for an item or service that has not yet been furnished?
☐ Yes If Yes, skip to Block 9.
☐ No If No, Specific Dates of Service:

9. If the request involves authorization for a prescription drug under Medicare Part D, would application of the standard appellate timeframe seriously jeopardize the beneficiary's life, health, or ability to regain maximum function (as documented by a physician) such that expedited review is appropriate? ☐ Yes ☐ No

I request that the Medicare Appeals Council review the ALJ's ☐ decision or ☐ dismissal order [check one] dated_____. I disagree with the ALJ's action because (specify the parts of the ALJ's decision or dismissal you disagree with and why you think the ALJ was wrong):

(Attach additional sheets if you need more space)

PLEASE ATTACH A COPY OF THE ALJ DECISION OR DISMISSAL ORDER YOU ARE APPEALING.

DATE			DATE		
APPELLANT'S NAME (the party requesting review)			REPRESENTATIVE'S NAME (include signed appointment of representative if not already submitted)		
ADDRESS			ADDRESS		
CITY, STATE, ZIP CODE			CITY, STATE, ZIP CODE		
TELEPHONE NUMBER	FAX NUMBER	E-MAIL	TELEPHONE NUMBER	FAX NUMBER	E-MAIL

(SEE FURTHER INSTRUCTIONS ON PAGE 2)

If you have additional evidence, submit it with this request for review. If you need more time, you must request an extension of time in writing now, explaining why you are unable to submit the evidence or legal argument now.

If you are a provider, supplier, or a beneficiary represented by a provider or supplier, and your case was reconsidered by a Qualified Independent Contractor (QIC), the Medicare Appeals Council will not consider new evidence related to issues the QIC has already considered unless you show that you have a good reason for submitting it for the first time to the Medicare Appeals Council.

IMPORTANT: Include the HICN or MBI and ALJ Appeal Number on any letter or other material you submit.

This request must be received within 60 calendar days after you receive the ALJ's decision or dismissal, unless we extend the time limit for good cause. We assume you received the decision or dismissal 5 calendar days after it was issued, unless you show you received it later. If this request will not be received within 65 calendar days from the date on the decision or dismissal order, please explain why on a separate sheet.

You must file your request for review in writing with the Medicare Appeals Council at:

Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6127
Cohen Building Room G-644
330 Independence Ave., S.W.
Washington, D.C. 20201

You may send the request for review by U.S. Mail, a common carrier such as FedEx, or by fax to (202) 565-0227. If you send a fax, please do not also mail a copy. ***You must send a copy of your appeal to the other parties and indicate that all parties, to include all beneficiaries, have been copied on the request for review. For claims involving multiple beneficiaries, you may submit a copy of the cover letters issued or a spreadsheet of the beneficiaries and addresses who received a copy of the request for review.***

If you have any questions about your request for review or wish to request expedited review of a claim involving authorization of your prescription drug under Medicare Part D, you may call the Medicare Appeals Council's staff in the Medicare Operations Division of the Departmental Appeals Board at (202) 565-0100. You may also visit our web site at www.hhs.gov/dab for additional information on how to file your request for review.

PRIVACY ACT STATEMENT

The collection of information on this form is authorized by the Social Security Act (section 205(a) of title II, section 702 of title VII, section 1155 of Title XI, and sections 1852(g)(5), 1869(b)(1), 1871, 1872, and 1876(c)(5)(B) of title XVIII, as appropriate). The information provided will be used to further document your claim. Information requested on this form is voluntary, but failure to provide all or any part of the requested information may affect the determination of your claim. Information you furnish on this form may be disclosed by the Department of Health and Human Services or the Social Security Administration to another person or governmental agency only with respect to programs under the Social Security Act and to comply with Federal laws requiring the disclosure of information or the exchange of information between the Department of Health and Human Services, the Social Security Administration, or other agencies.

Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Phoenix, AZ

Appeal of:	WESTFIELD FOOT & ANKLE SPECIALISTS,LLC	OMHA Appeal No.:	3-12502456807
Beneficiary:	Multiple	Medicare Part:	B
Medicare No.:	Multiple	Before:	ELI BRUCH Administrative Law Judge

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To protect beneficiary privacy, names and references to other individuals have been removed from the beneficiary copies of the Administrative Record and Exhibit List.

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Procedural - CMS Levels: Tursi consulting info	File 32	428 : 448

Non-Exhibit Records	File Name	Administrative File Reference Page Range
Records not considered: Duplicate evidence: med records	File 27	736 : 859
Records not considered: Duplicate evidence: Dr Marshall brief	File 32	211 : 249
Records not considered: Duplicate evidence: Cooper CV	File 32	426 : 427
Records not considered: Duplicate evidence: med records	File 32	449 : 472

To protect beneficiary privacy, names and references to other individuals have been removed from the beneficiary copies of the Administrative Record and Exhibit List.

Index of the Administrative Record and Exhibit List

Exhibit Records for beneficiary H. [redacted]	File Name	Administrative File Reference Page Range
Medical & Related: Medical Records: O[redacted]	File 23	1 : 34
Medical & Related: Medical Records: O[redacted]	File 26	5 : 6
Procedural - CMS Levels: Redetermination: O[redacted]	File 27	451 : 607
Procedural - CMS Levels: denial instructions: O[redacted]	File 31	409 : 415
Procedural - CMS Levels: Tursi consulting info	File 32	428 : 448

Non-Exhibit Records	File Name	Administrative File Reference Page Range
Records not considered: Duplicate evidence: med records	File 27	618 : 683
Records not considered: Duplicate evidence: med records	File 27	996 : 1063
Records not considered: Duplicate evidence: med records	File 31	135 : 164
Records not considered: Duplicate evidence: Dr Marshall brief	File 32	211 : 249
Records not considered: Duplicate evidence: redet copies	File 32	405 : 425
Records not considered: Duplicate evidence: Cooper CV	File 32	426 : 427
Records not considered: Duplicate evidence: med records	File 32	541 : 573
Records not considered: Duplicate evidence: med records	File 32	541 : 573

To protect beneficiary privacy, names and references to other individuals have been removed from the beneficiary copies of the Administrative Record and Exhibit List.

Index of the Administrative Record and Exhibit List

Exhibit Records for beneficiary J. D[redacted]	File Name	Administrative File Reference Page Range
Medical & Related: Medical Records: D[redacted]	File 12	1 : 27
Medical & Related: Medical Records: D[redacted]	File 26	6 : 7
Medical & Related: Medical Records: D[redacted]	File 31	47 : 77
Procedural - CMS Levels: Redetermination: D[redacted]	File 27	91 : 216
Procedural - CMS Levels: denial instructions: D[redacted]	File 31	388 : 394
Procedural - CMS Levels: Request for Reconsideration	File 32	60 : 106
Procedural - CMS Levels: Tursi consulting info	File 32	428 : 448

Non-Exhibit Records	File Name	Administrative File Reference Page Range
Records not considered: Duplicate evidence: med records	File 27	684 : 735
Records not considered: Duplicate evidence: med records	File 27	860 : 911
Records not considered: Duplicate evidence: Dr Marshall brief	File 32	211 : 249
Records not considered: Duplicate evidence: redet copies	File 32	280 : 324
Records not considered: Duplicate evidence: Cooper CV	File 32	426 : 427
Records not considered: Duplicate evidence: med records	File 32	473 : 498

To protect beneficiary privacy, names and references to other individuals have been removed from the beneficiary copies of the Administrative Record and Exhibit List.

ATTACHMENT A

Beneficiary Name	Medicare No.	Date(s) of Service
O[redacted], H.	*****8137A	01/21/2021 - 03/19/2021
L[redacted], A.	*****5089TA	03/10/2021 - 09/08/2021
DA[redacted], J.	*****6967B	09/02/2020 - 03/17/2021
A[redacted], B.	*****7266A	07/09/2021 - 08/27/2021

Attachment B

Claim Number	Initials	Date of Service	Procedure Code	ALJ Decision
9722083900037	E.A.	08/20/21	15275	Favorable
9722083900037	E.A.	08/20/21	Q4197	Favorable
9722083900038	E.A.	08/13/21	15275	Favorable
9722083900038	E.A.	08/13/21	Q4197	Favorable
9722083900039	E.A.	08/27/21	15275	Favorable
9722083900039	E.A.	08/27/21	Q4197	Favorable
9722083900040	E.A.	07/24/21	15275	Favorable
9722083900040	E.A.	07/24/21	Q4197	Partially Favorable[1]
9722083900041	E.A.	08/06/21	15275	Favorable
9722083900041	E.A.	08/06/21	Q4197	Favorable
9722083900042	E.A.	07/09/21	15275	Favorable
9722083900042	E.A.	07/09/21	Q4197	Partially Favorable[2]
9722083900028	J.D.	01/20/21	Q4159	Favorable
9722083900029	J.D.	01/27/21	15275	Favorable
9722083900029	J.D.	01/27/21	Q4159	Favorable
9722083900030	J.D.	09/02/20	Q4159	Favorable
9722083900030	J.D.	09/02/20	15275	Favorable
9722083900031	J.D.	12/16/20	Q4197	Favorable
9722083900031	J.D.	12/16/20	15275	Favorable
9722083900032	J.D.	01/06/21	15275	Favorable
9722083900032	J.D.	01/06/21	Q4159	Favorable
9722083900033	J.D.	03/17/21	Q4159	Favorable
9722083900033	J.D.	03/17/21	15275	Favorable
9722083900034	J.D.	02/11/21	Q4159	Favorable

[1] 25 units
[2] 25 units

Claim Number	Initials	Date of Service	Procedure Code	ALJ Decision
9722083900034	J.D.	02/11/21	15275	Favorable
9722083900035	J.D.	02/24/21	Q4159	Favorable
9722083900035	J.D.	02/24/21	15275	Favorable
9722083900036	J.D.	03/03/21	Q4159	Favorable
9722083900036	J.D.	03/03/21	15275	Favorable
9722083472000	A.L.	08/25/21	Q4197	Unfavorable
9722083472000	A.L.	08/25/21	15275	Unfavorable
9722083472000	A.L.	08/25/21	Q4197	Unfavorable
9722083900013	A.L.	03/17/21	Q4197	Unfavorable
9722083900013	A.L.	03/17/21	15275	Unfavorable
9722083900014	A.L.	04/07/21	Q4159	Unfavorable
9722083900015	A.L.	04/14/21	Q4159	Unfavorable
9722083900016	A.L.	04/21/21	Q4159	Unfavorable
9722083900017	A.L.	05/05/21	Q4159	Unfavorable
9722083900018	A.L.	05/12/21	15275	Unfavorable
9722083900018	A.L.	05/12/21	Q4159	Unfavorable
9722083900019	A.L.	05/19/21	15275	Unfavorable
9722083900019	A.L.	05/19/21	Q4159	Unfavorable
9722083900020	A.L.	05/27/21	15275	Unfavorable
9722083900020	A.L.	05/27/21	Q4159	Unfavorable
9722083900021	A.L.	08/04/21	Q4197	Unfavorable
9722083900021	A.L.	08/04/21	15275	Unfavorable
9722083900021	A.L.	08/04/21	Q4197	Unfavorable
9722083900022	A.L.	08/18/21	Q4197	Unfavorable
9722083900022	A.L.	08/18/21	15275	Unfavorable
9722083900022	A.L.	08/18/21	Q4197	Unfavorable
9722083900023	A.L.	08/11/21	Q4197	Unfavorable
9722083900023	A.L.	08/11/21	15275	Unfavorable
9722083900023	A.L.	08/11/21	Q4197	Unfavorable
9722083900024	A.L.	03/10/21	Q4159	Unfavorable
9722083900024	A.L.	03/10/21	15275	Unfavorable

Claim Number	Initials	Date of Service	Procedure Code	ALJ Decision
9722083900025	A.L.	03/25/21	Q4197	Unfavorable
9722083900025	A.L.	03/25/21	Q4197	Unfavorable
9722083900025	A.L.	03/25/21	15275	Unfavorable
9722083900026	A.L.	09/01/21	Q4197	Unfavorable
9722083900026	A.L.	09/01/21	15275	Unfavorable
9722083900026	A.L.	09/01/21	Q4197	Unfavorable
9722083900027	A.L.	09/08/21	Q4197	Unfavorable
9722083900027	A.L.	09/08/21	15275	Unfavorable
9722083900027	A.L.	09/08/21	Q4197	Unfavorable
9722083900043	H.O.	01/21/21	15277	Favorable
9722083900043	H.O.	01/21/21	Q4159	Favorable
9722083900044	H.O.	02/04/21	15277	Favorable
9722083900044	H.O.	02/04/21	Q4159	Favorable
9722083900048	H.O.	01/28/21	15277	Favorable
9722083900048	H.O.	01/28/21	Q4159	Favorable
9722083900049	H.O.	03/19/21	Q4159	Favorable

EXHIBIT "C"

Check Number 9937 In The Amount Of $345,533.46			
Financial Control Number	Patient Account Number	Date of Service	Amount Applied
869623292660024CN	11273329A	June 1, 2021	9,805.80
869623292660024CNX	Interest		297.24
869623292660024IC	Interest		594.48
869623292660025CN	11275438A	June 8, 2021	9,805.80
869623292660025CNX	Interest		396.32
869623292660025IC	Interest		594.48
869623292660027CN	11277948A	June 3, 2021	22,699.09
869623292660027CNX	Interest		688.08
869623292660027IC	Interest		1,376.16
869623292660028CN	11277949A	June 10, 2021	22,699.09
869623292660028CNX	Interest		688.08
869623292660028IC	Interest		1,376.16
869623292660029CN	11281594A	June 17, 2021	22,699.09
869623292660029CNX	Interest		688.08
869623292660029IC	Interest		1,376.16
869623292660030CN	11285218A	June 24, 2021	22,699.09
869623292660030CNX	Interest		688.08
869623292660030IC	Interest		1,376.16
869623292660031CN	11288548A	June 18, 2021	22,699.09
869623292660031CNX	Interest		917.44
869623292660031IC	Interest		1,376.16
869623292660032CN	11294384A	July 22, 2021	11,017.89
869623292660032CNX	Interest		386.77
869623292660032IC	Interest		667.98
869624004660021CN	11233454A	February 11, 2021	7,953.51
869624004660021CNX	Interest		115.36
869624004660021IC	Interest		692.16
869722083472000	11307139A	August 25, 2021	5,378.69
869722083472000-I	Interest		81.8
869722083900013	11241713A	March 17, 2021	5,177.29
869722083900013-I	Interest		78.74
869722083900014	11253093A	April 7, 2021	5,639.20
869722083900014-I	Interest		85.76
869722083900015	11257067A	April 14, 2021	5,639.20
869722083900015-I	Interest		85.76
869722083900016	11257117A	April 21, 2021	5,639.20
869722083900016-I	Interest		85.76
869722083900017	11262363A	May 5, 2021	5,639.20
869722083900017-I	Interest		85.76
869722083900018	11264863A	May 12, 2021	5,781.49
869722083900018-I	Interest		87.92
869722083900019	11269923A	May 19, 2021	5,781.49
869722083900019-I	Interest		87.92
869722083900020	11271286A	May 27, 2021	5,781.49

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869722083900020-I	Interest		87.92
869722083900021	11301097A	August 4, 2021	5,177.29
869722083900021-I	Interest		78.74
869722083900022	11302590A	August 18, 2021	5,177.29
869722083900022-I	Interest		78.74
869722083900023	11308798A	August 11, 2021	5,177.29
869722083900023-I	Interest		78.74
869722083900024	11239203A	March 10, 2021	5,781.49
869722083900024-I	Interest		87.92
869722083900025	11259494A	March 25, 2021	5,177.29
869722083900025-I	Interest		78.74
869722083900026	11311046A	September 1, 2021	5,177.29
869722083900026-I	Interest		78.74
869722083900027	11311047A	September 8, 2021	5,177.29
869722083900027-I	Interest		78.74
869722083900032	11216220A	January 6, 2021	21.45
869722083900032-I	Interest		0.32
869722083900037	11304347A	August 20, 2021	5,177.29
869722083900037-I	Interest		78.74
869722083900038	11306843A	August 13, 2021	5,177.29
869722083900038-I	Interest		78.74
869722083900039	11308802A	August 27, 2021	5,030.14
869722083900039-I	Interest		78.74
869722083900039CN	11308802A	August 27, 2021	147.15
869722083900039CNX	Interest		23.52
869722083900039IC	Interest		6.72
869722083900040	11295000A	July 24, 2021	5,982.89
869722083900040-I	Interest		90.98
869722083900041	11321579A	August 6, 2021	5,177.29
869722083900041-I	Interest		78.74
869722083900042	11288546A	July 9, 2021	5,982.89
869722083900042-I	Interest		90.98
869722083900043	11217614A	January 21, 2021	145.28
869722083900043-I	Interest		2.2
869722083900045	11188388A	November 20, 2020	10,724.35
869722083900045-I	Interest		163.1
869722083900046	11210844A	December 23, 2020	22,858.20
869722083900046-I	Interest		347.64
869722083900047	11216222A	January 7, 2021	22,719.32
869722083900047-I	Interest		345.52

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